K040404

MAY - 4 2004

15. 510(k) Summary

Date Summary Prepared

February 6, 2004

Submitter's Name and Address

Philips Medical Systems
Cardiac and Monitoring Systems
Cardiac Resuscitation
3000 Minuteman Road
Andover, MA 01810-1099

Contact Person

Peter Ohanian
Philips Medical Systems
Cardiac and Monitoring Systems
Cardiac Resuscitation
Telephone: (978) 659-3397
Facsimile: (978) 659-4878

Device Name

Proprietary Name:	Cadex Battery Charger for Philips HeartStart Batteries
Common Name:	Battery Charger for Defibrillator Batteries
Classification Names:	Arrhythmia Detection & Alarms (Automatic External Defibrillator

Predicate Devices

The legally marketed devices to which Philips Medical Systems claims equivalence for the Cadex Battery Charger for Philips HeartStart Batteries are as follows:

- ZOLL Medical Corp., PowerBase™
- Medtronic Physio-Control Battery Support System 2

The design of the Cadex Battery Charger for Philips HeartStart Batteries is substantially equivalent in safety and performance to the devices listed above.

Device Description

The Cadex Battery Charger for Philips HeartStart Batteries is used to charge and analyze rechargeable batteries used in Philips HeartStart defibrillators. The Battery Charger consists of a commercially available battery charger and an adapter specifically designed to interface with the Philips HeartStart batteries. The battery charger is available in 2- and 4-bay models, which allow for the simultaneous charging of up to 4 batteries. The adapters allow for the mechanical interface between the battery and the battery charger. The adapters also contain the software that allows the battery charger to charge the battery using the appropriate algorithm for the type of battery being charged. The battery charger also analyzes a battery to determine its capacity.

Intended Use

The Cadex Battery Charger for Philips HeartStart Batteries is used to recharge and analyze rechargeable batteries that are used with Philips HeartStart manual defibrillator/monitors.

Comparison of Technology Characteristics

The Cadex Battery Charger for Philips HeartStart Batteries employs the same fundamental scientific technologies as the commercially available predicate devices used for comparison.

Tests Used in Determination of Substantial Equivalence

The tests used in the determination of substantial equivalence included only bench testing. Bench testing includes hardware and software testing demonstrating that the performance of the device meets its specification

Conclusion from Testing

Based on the results of the testing described above, it is concluded that the Cadex Battery Charger for Philips HeartStart Batteries does not raise any different questions regarding the safety or effectiveness as compared with the predicate devices. It is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Philips Medical Systems
c/o Mr. Peter Ohanian
Director, Quality and Regulatory Affairs
Cardiac and Monitoring Systems
Cardiac Resuscitation
3000 Minuteman Road, MS 0222
Andover, MA 01810

Re: K040404
Trade Name: Cadex Battery Charger for Philips HeartStart Batteries
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrythmia Detector and Alarm
Regulatory Class: III (three)
Product Code: MKJ
Dated: March 11, 2004
Received: March 12, 2004

Dear Mr. Ohanian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act 4 or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): To be assigned K040404

Device Name: Cadex Battery Charger for Philips HeartStart Batteries

Indications for Use: The Cadex Battery Charger for Philips HeartStart Batteries is used to recharge and analyze rechargeable batteries that are used with Philips HeartStart manual defibrillator/monitors.

Prescription Use: Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040404